

I. REMARKS

In the Office Action mailed March 12, 2009 the Office Action rejected claims 81, 83-86, 89, 91, 92, and 94-96 as being obvious and unpatentable over Hoyns (6,766,186) in view of Foerster (2001/0034528). The Office Action further rejected claims 82, 87, 88, 90, and 93 as being obvious and unpatentable over Hoyns (6,766,186) in view of Foerster (2001/0034528) and further in view of Voegle (6,425,903). Applicant is presenting new claims 97-100. Support for the new claims under 35 U.S.C. § 112 can be found in the specification in Paragraph 0052 and Figures 1, 11C, 12A, 13A, and 13B. Applicant believes that the new set of claims is patentable. The foregoing amendments are taken in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicant would otherwise be entitled in view of the prior art.

II. CLAIM REJECTIONS – 35 USC § 103

The Office Action rejected claim 81 and its dependents stating the present invention is obvious and unpatentable over Hoyns (6,766,186) in view of Foerster (2001/0034528). The Office Action fails to make a *prima facie* rejection under 35 USC § 103 for the reasons detailed below. Without acquiescence to this suggestion Applicant has amended claim 81 to further distinguish over the art of record. Support for the amendment under 35 U.S.C. § 112 can be found in the specification in Paragraph 0080 and Figures 1, 3, 7, 8, 11C, 13A, 13B, and 15.

a) Incorrect Fact Findings and Lack of Evidence

The Office Action fails to address multiple structures listed in claim 81. The law requires that “[a]ll words in a claim **must** be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970)(Emphasis added). The Office Action does not show where any of the references of record teach any of the following limitations. Specifically, the Office Action fails to show a metal structure that: (1) resides entirely within the delivery tube prior to being driven through the exit opening; (2) deploys through a hole of the delivery device; (3) in both an original pre-deployment state and a post-deployment state, the first ends of the **first and second arc segments** project in a direction outward relative to the clip axis opposite to that of the

second ends of the first and second arc segments, the first ends of the first and second arc segments project in a direction generally away from the second ends of the **first and second arc segments**; (4) **while it resides within the delivery tube prior to being driven through the exit opening the arc segments are arcuate**; and (5) the first and second ends of the **first and second arc segments penetrate breast tissue** after being driven through the exit opening of the delivery tube.

A proper *prima facie* case of obviousness has not been presented because at least five elements of claim 81 have been completely ignored in the Office Action. The evidence cited in the art cannot support the rejection. For example, claim 81 states that the clip, “while it resides within the delivery tube prior to being driven through the exit opening the arc segments are arcuate.” The Office Action combined the clip of Hoyns with the clip of Foerster to reject claim 81; however, the Forester clip as illustrated in Fig. 12 is not arcuate while in the delivery tube prior to deployment. Therefore, the evidence does not support the premise that the Foerster clip is arcuate while in the delivery tube, as required by the claims.

b) Claims are not Obvious Under the Law

Hoyns and Foerster are not combinable under the law. Furthermore, the Office Action has failed to explain how the clip of Hoyns modified in view of the disclosure of Foerster would be combined and still function.

Under *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007) in light of *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), Applicants believe that a proper 35 U.S.C. § 103 rejection was not made. Although the teaching-suggestion-motivation (TSM) test requirements as applied in *KSR* have been altered to be applied in a less rigid manner, the references still are not combinable, especially because Hoyns in view of Foerster does not address each of the claimed differences. The Court in *KSR* said:

Often, it will be necessary...to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an **apparent reason** to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis **should be made explicit**.

KSR, 82 USPQ2d at 1395 (emphasis added). Foremost, the Office Action fails to point out how Hoyns can be combined with Foerster. No explicit analysis was stated in the

Office Action describing the combination Hoyns and Foerster clip. The Office Action does not explain how the new, modified, clip would operate. For example, the Office Action suggests that Foerster discloses an arc shaped clip, but there is no discussion about multiple arc segments. The present invention claims a first arc segment and a second arc segment. However, the Office Action only discusses one arc segment in the rejection. The Office Action does not disclose how or why a person skilled in the art would employ a second arcuate arc segment as required by the claims. The Office Action further fails to disclose: (1) how will the two arc segments are held together, (2) where will the two arc segments be attached, and (3) what motivation does a person skilled in the art have to modify the clips in this manner.

Furthermore, there are some practical problems with the proposed combination of Hoyns and Foerster. First, Hoyns secures the wires together by tubing, welding, soldering, adhesive bonding, or crimping the **central portions or middle portions** of the clip together. (see Hoyns column 6, lines 9 and 13). However, the clip of Forester has a center coil 92. How will the center coil fit in the tubing so that the clip can still be loaded in a needle and function, especially when, as stated in the Office Action, "the tubing is about half the length of the entire clip"? See the Office Action dated 03/12/2009 page 3. It is believed that if the clip of Foerster was modified as suggested by the Office Action that the Foerster clip would no longer function because it could not be folded and thus would not spring. Therefore, it is believed that Hoyns teaches away from the suggested modification of Foerster, since the modification to Foerster would render the clip of Foerster unsatisfactory for its intended purpose. MPEP 2143.01.

Next, there is no evidence presented on how the new clip would function if a weld, solder, adhesive, or crimp was employed. The Office Action does not present evidence as to how: (a) the two arc segments are held together; (b) the springing action is not impeded; and (c) the Hoyns and Foerster hybrid clip prevents migration. The functioning of Hoyns and Foerster are inconsistent. Hoyns teaches a majority of the clip is connected to hold two segments together, and Foerster teaches a one segment clip that is tightly folded to fit within a delivery tube so that the clip will spring. These inconsistent teachings are not reconciled by the Office Action. Furthermore, the Office Action does not teach how the weld, solder, adhesive, or crimp of Hoyns would cover the central portions or middle portions of the Foerster clip and still function. Again, how will the center coil be used if the central portion or middle portions of the clip are welded, soldered, adhered, or crimped together so that the clip can still be loaded in a needle and function, especially when, as

stated in the Office Action, "the tubing is about half the length of the entire clip"? See the Office Action dated 03/12/2009 page 3 (It is believed that the weld, solder, adhesive, or crimp will be proportionally the same amount of the clip as illustrated in Figures 9, 13, 14). Both clips function in a different manner, as stated above, and these differences are not reconciled in the Office Action.

Moreover, Hoyns and Foerster are not combinable because they teach away from each other. The Hoyns and Foerster teach clips that have first and second ends pointing in different directions. The Office Action has not presented any evidence that either reference has any suggestion or motivation to change the direction the ends point in the post-deployment state. Further objective evidence that the modification to Hoyns is not obvious can be found in Paragraphs 11a, 11c, and 11d. Therefore, it is believed that Hoyns is not combinable with Foerster, and the modifications as suggested in the Office Action would render the clip of Foerster or Hoyns unsatisfactory for their intended purpose.

MPEP 2143.01.

c) Improper Application of KSR

Applicant believes that the Office Action did not set forth an appropriate analysis to satisfy the Supreme Court's requirements from *KSR International co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007). The Office has the burden to explicitly analyze:

. . . interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")....

Applicant believes the rejections to date are mere conclusory statements absent any "articulated reasoning with some rational underpinning to support the legal conclusions of obviousness." The Office Action fails to point out with any particularity where Hoyns or Foerster teach a clip that "is configured so that it deploys through a **side hole** of the delivery device along a **ramp**" as found in claims 83, 87, 89, and 91. Furthermore, Applicant points to the Paragraph 12 of the Rule 132 Affidavit as objective evidence that the clip of Hoyns could not be delivered using a side hole along a ramp.

Moreover, Applicant is skeptical that the clip of Hoyns could be delivered through a side hole when "the tubing is about half the length of the entire clip." See the Office Action dated 03/12/2009 page 3. Applicant further believes that the tubing would make a side deployment up a ramp difficult due to the rigidity and length of the tubing.

The Office Action further fails to state where Hoyns, Foerster, or Voegele teach a clip as that "is configured so that while within the delivery tube the clip **contacts an inner wall of the delivery tube**" as found in claims 84, 88, and 89. The Office Action states that it would have been obvious to create the clip in the Selis Application; however, the points listed above were not even discussed in the Office Action. Therefore, a proper rejection under KSR was not made.

III. CONCLUSIONS

In view of Applicant's remarks, the Examiner's previously presented rejections are believed to be rendered moot. Accordingly, Applicant submits that the present application is in condition for allowance and requests that the Examiner pass the case to issue at the earliest convenience. Should the Examiner have any question or wish to further discuss this application, Applicant requests that the Examiner contact the undersigned at (248) 292-2920.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge Deposit Account No. 50-1097 for any fee which may be due.

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